

MAR 24 1999

Date of Approval: _____

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 138-935

Chlortetracycline (CTC)

Type A Medicated Article

Sponsored by:

Pennfield Oil Company
Omaha, Nebraska 68144

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION

NADA Number 138-935

Sponsor: Pennfield Oil Company
Omaha, Nebraska 68144

Generic Name: Chlortetracycline Pre-mix

Trade Name: Pennchlor Type A Medicated Article

Marketing Status: OTC

Effect of the Supplement: Changes the withdrawal time ~~from~~ 10 days to one day withdrawal period for cattle

2. INDICATIONS FOR USE: See below

3. A. DOSAGE FORM: Type A Medicated Article

B. ROUTE OF ADMINISTRATION: Oral - For use in Type C medicated feed

c. RECOMMENDED DOSAGES:

<u>Dosage</u>	<u>Indication for use</u>
<u>Cattle, beef cattle,</u> <u>And nonlactating dairy</u> Cattle”	
0.1 mg/lb b.w.	Calves (up to 250 lbs.): For an increased rate of weight gain and improved feed efficiency.
25-70 mg/head	Calves(250-400 lbs.): For an increased rate of weight gain and improved feed efficiency
70 mg/head/day	For Growing Cattle(over 400 lbs.):

For an increased weight gain and improved feed efficiency and the reduction of liver condemnation due to liver **abcesses**.

350 mg/head/day For Beef Cattle: Control of bacterial pneumonia associated with shipping fever complex caused by Pasteurella spp susceptible to chlortetracycline.

350 mg/head/day For Beef Cattle(under 700 lbs.): Control of active infection of **anaplasmosis** caused by Anaplasma marginale susceptible to chlortetracycline.

0.5 mg/lb/bw For Beef Cattle(over 700 lbs.): Control of active infection of **anaplasmosis** caused by Ananplasma marginale susceptible to chlortetracycline.

10 mg/lb/bw For Calves, beef and **nonlactating** dairy Cattle: For treatment of bacterial enteritis caused by Escherichia coli and bacterial pneumonia caused by Pasteurella multocida susceptible to chlortetracycline.

Withdrawal period-one day (1-day) for cattle and calves

4. EFFECTIVENESS: No further effectiveness data were required.
5. ANIMAL SAFETY: No **further** safety data were required.
6. HUMAN FOOD SAFETY:

A. Tolerances for Residues

Recently, the Center for Veterinary Medicine(CVM) revised the tolerances for tetracycline drugs (61 FR 67453). Based on that reevaluation, tolerances for total tetracycline residues in tissues are established as follows:

2 ppm in muscle
6 ppm in liver
12 ppm in kidney
12 ppm in fat

B. Studies to Establish a Withdrawal Time

Title: Chlortetracycline 50 g/ton for dried fermentation solids

Study Number: WARF Institute Number 1092938

Date: October 30, 1972

Study design: Twelve steers were used in the study. The study was begun when animals weighed approximately 500lbs. and continued for 10 months, by which time the test animals weighed 900-1000 lbs. Calves were assigned to one of three treatment groups. Calves in the treatment groups were fed 175 mg chlortetracycline/head/day as atop dress on a mile-based fattening ration. Three animals served as untreated controls. Animals were slaughtered within 12 hours following the withdrawal of medicated feed, 24 hours after the withdrawal of medicated feed and 48 hours after the withdrawal of medicated feed. At slaughter the following samples were collected: blood plasma (citrate); liver, all; kidneys, both; muscle; fat. Tissue samples were finely ground and assayed for CTC using the official analytical method for residues. Residue values are summarized in Table 1.

Table 1: Mean tissue residue data summary

Withdrawal wal (hours)	Muscle	Liver	Kidney	Fat
Control	-	-	-	-
12	0.028	0.073	0.078	-
24			<0.05	-
48				

C. Calculating the Withdrawal Time

The calves used in the WARF study were not dosed with the maximum codified dose for chlortetracycline. For the withdrawal time analysis, the reported tissue residue values were dose-adjusted to the maximum approved dose for chlortetracycline in cattle (*i. e.*, 175 mg/hd/day for a 1000 lb calf= 0.175 mg/lb vs. 10 mg/lb). Using a dose correction factor of 57X, the resulting dose-adjusted residues are 1.6 ppm in muscle (vs. a tolerance of 2 ppm), 4.16 ppm in liver (vs. a tolerance of 6 ppm), and 4.45 ppm in kidney (vs. a tolerance of 12 ppm) at zero withdrawal. The deficiencies associated with the WARF study relative to the current residue depletion study

standards preclude the assignment of a zero withdrawal for the use of this chlortetracycline product in cattle. The mean dose-corrected kidney residue at 24 hours withdrawal is 24% of the codified tolerance (i.e., 2.85 ppm vs. a tolerance of 12 ppm) and supports a withdrawal period of 24 hours (1 -day) for doses of chlortetracycline in feed up to 10 mg/lb.

D. Regulatory Analytical Methods for Residues

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Bacillus cereus var mycoides* (ATCC 11778). The method is found in Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports and Protocols, Revised October 1968, Reprinted December 1974, Nation Center for Antibiotic and Insulin Analysis, FDA, Washington, DC 20204.

7. AGENCY CONCLUSIONS:

This supplemental NADA satisfies the requirements of section 512 of the Act and demonstrates that Pennchlor Type A Medicated Article when used under its proposed conditions of use, is safe and effective for the labeled indications. The supplemental approval provides for the use of this chlortetracycline premix fed to cattle with a one day withdrawal period.

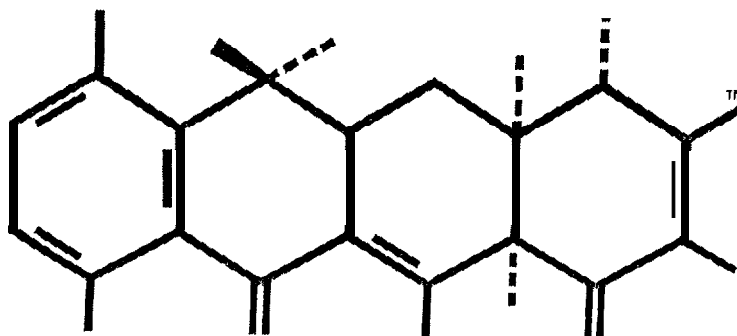
Under the Center's supplemental approval policy [21 CFR 514. 10f] this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. However, the approval did require a reevaluation of the human food safety data in the parent application. The shorter withdrawal "period was based on the revised tolerances for chlortetracycline; 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney.

8. Labeling: See Attachment(s)

Pennchlor 50TM

***** CHLORTETRACYCLINE

MEAL
(Type A Medicated Article)



FOR USE IN THE MANUFACTURE OF MEDICATED FEEDS

ACTIVE DRUG INGREDIENTS:
Chlortetracycline as Chlortetracycline Calcium Complex equivalent 1050 gram:Chlortetracycline Hydrochloride/lb

INGREDIENTS:
Chlortetracycline, Calcium Carbonate, Roughage Products end Mineral Oil,

See back panel for directions and warnings.

CAUTION: **For use In Dry Feeds ONLY -NOT FOR USE IN LIQUID FEED SUPPLEMENTS.**

NADA 138-935 APPROVED BY FDA

Restricted Drug: (California) -
Use only as directed

NET WT.
50 lb (22.7 kg)

PennField[®] 

Pennchlor 50™

CHLORTETRACYCLINE

DIRECTIONS FOR USE

Indications for Use	Use Levels of Chlorotetracycline	Lbs. of Pennchlor 50™ per ton	Indications for Use	Use Levels of Chlorotetracycline	Lbs. of Pennchlor 50™ per ton
CHICKENS For Broiler/layer chickens: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.2-1.0	SWINE For Growing Swine: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.20-1.0
For Chickens: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	100-200 g/ton	2.0-4.0	For Swine: Reducing the incidence of cervical lymphadenitis (owl abscesses) caused by <i>Campylobacter</i> susceptible to chlorotetracycline. (Feed continuously for 14 days)	50-100 g/ton	1.0-2.0
For Chickens: Control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	200-400 g/ton	4.0-8.0	For Breeding Swine: Control of leptospirosis (reducing the instances of abortions and shedding of leptospirae) caused by <i>Leptospira</i> susceptible to chlorotetracycline. (Feed continuously for 14 days)	400 g/ton	8.0
For Chickens: Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlorotetracycline. (Feed for 5 days) WARNING: Do not feed to chickens producing eggs for human consumption. Withdraw 24 hours prior to slaughter.	500 g/ton	10.0	For Swine: Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Feed for not more than 14 days) WARNING: Zero-day withdrawal period.	10 mg/lb body weight/day	
TURKEYS For Turkeys: Growing Turkeys: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.2-1.0	CALVES, BEEF CATTLE, AF40, NONLACTATING DAIRY CATTLE WARNING: A WITHDRAWAL PERIOD HAS NOT BEEN ESTABLISHED FOR THIS PRODUCT IN PRE-RUMINATING CALVES. DO NOT USE IN CALVES TO BE PROCESSED FOR VEAL.		
For Turkeys: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	200 g/ton	4.0	For Calves (up to 250 lbs.): For an increased weight gain and improved feed efficiency.	0.1 mg/lb body weight/day	
For Turkeys: Control of hemophilic caused by <i>Hemophilus meleagridis</i> susceptible to chlorotetracycline. (Feed continuously 7-14 days)	400 g/ton	8.0	For Calves (250-400 lbs.): For an increased weight gain and improved feed efficiency.	25-70 mg/head/day	
For Turkeys: Turkey poulters not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlorotetracycline.	400 g/ton	8.0	For Growing Cattle (over 400 lbs.): For an increased weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses. WARNING: Zero-day withdrawal period.	70 mg/head/day	
For Turkeys: Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus enteritis) susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	25 mg/lb body weight/day		For Cattle: For the control of bacterial pneumonia associated with shipping fever complex susceptible to chlorotetracycline.	350 mg/head/day	
SHEEP For Growing Sheep: For an increased rate of weight gain and improved feed efficiency.	20-50 g/ton	0.4-1.0	For Beef Cattle (under 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline.	350 mg/head/day	
For Breeding Sheep: Reducing the incidence of (vibronic) abortion caused by <i>Campylobacter fetus</i> infection susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.	80 mg/head/day		For Beef Cattle (over 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. WARNING: Withdraw 1 day prior to slaughter.	0.5 mg/lb body weight/day	
			For Calves, Beef, and Nonlactating Dairy Cattle: For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Treat for not more than 5 days). WARNING: Withdraw 1 day prior to slaughter.	10 mg/lb body weight/day	



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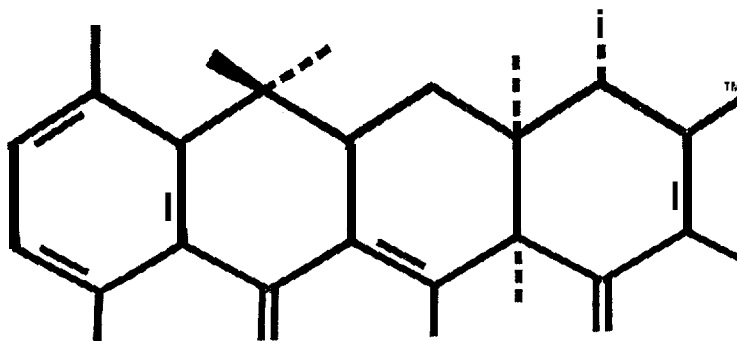
Distributed by
PennField Animal Health
14040 Industrial Rd.
Omaha, Nebraska 68144

Pennchlor



CHLORTETRACYCLINE

(Type A Medicated Article)



FOR USE IN THE MANUFACTURE OF MEDICATED FEEDS

ACTIVE DRUG INGREDIENTS

Chlortetracycline as Chlortetracycline Calcium Complex equivalent to 50 grams Chlortetracycline Hydrochloride/lb.
INGREDIENT%

Chlortetracycline, Calcium Carbonate, Roughage Products and Mineral Oil.

See back panel for directions and warnings.

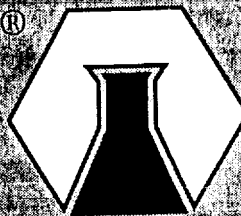
CAUTION: **For use in Dry Feeds ONLY - NOT FOR USE IN LIQUID FEED SUPPLEMENTS.**

NADA 138-935 APPROVED BY FDA

Restricted Drug: (California)
Use only as directed

NET WT.
50 lb (22.7 kg)

PennField®



Pennchlor 50-G™

CHLORTETRACYCLINE

DIRECTIONS FOR USE

Indications for Use	Use Levels of Chlorotetracycline	Lbs. of Pennchlor 50-G™ per ton	Indications for Use	Use Levels of Chlorotetracycline	Lbs. of Pennchlor 50-G™ per ton
CHICKENS For Broiler/layer chickens: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.2-1.0	SWINE For Growing Swine: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.20-1.0
For Chickens: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	100-200 g/ton	2.0-4.0	For Swine: Reducing the incidence of cervical lymphadenitis (owl abscesses) caused by <i>Campylobacter</i> susceptible to chlorotetracycline.	50-100 g/ton	1.0-2.0
For Chickens: Control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	200-400 g/ton	4.0-8.0	For Breeding Swine: Control of leptospirosis (reducing the instances of abortions and shedding of leptospire) caused by <i>Leptospira pomona</i> susceptible to chlorotetracycline. (Feed continuously for 14 days)	400 g/ton	8.0
For Chickens: Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlorotetracycline. (Feed for 5 days) WARNING: Do not feed to chickens producing eggs for human consumption. Withdraw 24 hours prior to slaughter.	500 g/ton	10.0	For Swine: Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Feed for not more than 14 days) WARNING: Zero-day withdrawal period.	10 mg/lb body weight day	
TURKEYS For Turkeys: Growing Turkeys: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.2-1.0	CALVES, BEEF CATTLE, AND NONLACTATING DAIRY CATTLE WARNING: A WITHDRAWAL PERIOD HAS NOT BEEN ESTABLISHED FOR THIS PRODUCT IN THE RUMINATING CALVES. DO NOT USE IN CALVES TO BE PROCESSED FOR VEAL.		
For Turkeys: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	200 g/ton	4.0	For Calves (up to 250 lbs.): For an increased weight gain and improved feed efficiency.	0.1 mg/lb body weight day	
For Turkeys: Control of hemorrhis caused by <i>Haemaphysalis meleagridis</i> susceptible to chlorotetracycline. (Feed continuously 7-14 days)	400 g/ton	8.0	For Calves (250-400 lbs.): For an increased weight gain and improved feed efficiency.	25-70 mg/head day	
For Turkeys: Turkey poulters not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlorotetracycline.	400 g/ton	8.0	For Growing Cattle (over 400 lbs.): For an increased weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses. WARNING: Zero-day withdrawal period.	70 mg/head day	
For Turkeys: Control of complicating bacterial organisms associated with blackcomb (irreversible enteritis, convulsant enteritis) susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	25 mg/lb body weight day		For Cattle: For the control of bacterial pneumonia associated with shipping fever complex susceptible to chlorotetracycline.	350 mg/head day	
SHEEP For Growing Sheep: For an increased rate of weight gain and improved feed efficiency.	20-50 g/ton	0.4-1.0	For Beef Cattle (under 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. WARNING: Withdraw 1 day prior to slaughter.	350 mg/head day	
For Breeding Sheep: Reducing the incidence of (vibronic) abortion caused by <i>Campylobacter fetus</i> infection susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.	80 mg/head day		For Beef Cattle (over 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. (Feed for not more than 5 days) WARNING: Withdraw 1 day prior to slaughter.	0.5 mg/lb body weight day	
			Calves, Nonlac: bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Feed for not more than 5 days) WARNING: Withdraw 1 day prior to slaughter.	10 mg/lb body weight day	



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PennField Animal Health

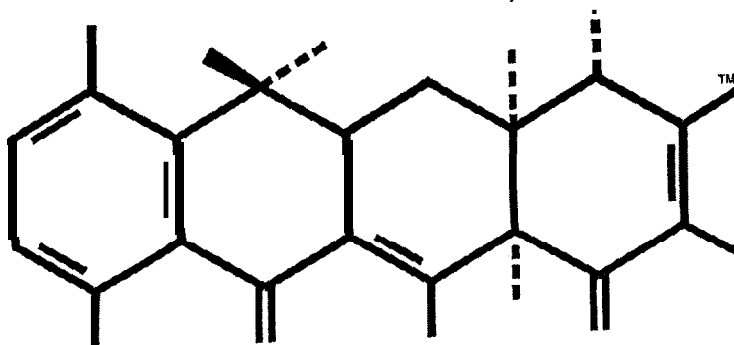
14040 Industrial Rd.
Omaha, Nebraska 68144

Pennchlor 60TM

..... CHLORTETRACYCLINE

MEAL

(Type A Medicated Article)



FOR USE IN THE MANUFACTURE OF MEDICATED FEEDS

ACTIVE DRUG INGREDIENTS:

Chlortetracycline as Chlortetracycline Calcium Complex equivalent to 60 grams Chlortetracycline Hydrochloride/lb.
INGREDIENTS:

Chlortetracycline, Calcium Catenate, Roughage Products and Mineral Oil.

See back panel for directions and warnings.

CAUTION: **For use in Dry Feeds ONLY** — NOT FOR USE IN LIQUID FEED SUPPLEMENTS.

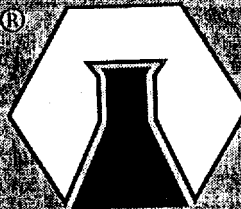
NADA 135935 APPROVED BY FDA

Restricted Drug: (California)

Use only as directed

NET WT.
50 lb (22.7 kg)

PennField[®]



Pennchlor 60™

CHLORTETRACYCLINE

Directions FOR USE

Indications for Use	Use Levels of Chlorotetracycline	lbs. of Pennchlor 60™ per ton	Indications for Use	Use Levels of Chlorotetracycline	lbs. of Pennchlor 60™ per ton
CHICKENS For Broiler/layer chickens: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.166-0.833	SWINE For Growing Swine: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.166-0.833
For Chickens: Control of infectious synovitis caused by <i>Mycoplasma agalactiae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	100-200 g/ton	1.666-3.333	For Swine: Reducing the incidence of cervical lymphadenitis (owl abscesses) caused by <i>Campylobacter</i> susceptible to chlorotetracycline.	50-100 g/ton	0.833-1.666
For Chickens: Control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	200-400 g/ton	3.333-6.666	For Breeding Swine: Control of leptospirosis (reducing the instances of abortions and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to chlorotetracycline. (Feed continuously for 14 days)	400 g/ton	6.666
For Chickens: Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlorotetracycline. (Feed for 5 days) WARNING: Do not feed to chickens producing eggs for human consumption. Withdraw 24 hours prior to slaughter.	500 g/ton	8.333	For Swine: Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Feed for not more than 14 days) WARNING: Zero-day withdrawal period.	10 mg/lb body weight/day	
TURKEYS For Turkeys: Growing Turkeys: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.166-0.833	CALVES, BEEF CATTLE, AND NONLACTATING DAIRY CATTLE WARNING: A WITHDRAWAL PERIOD HAS NOT BEEN ESTABLISHED FOR THIS PRODUCT IN PRE-RUMINATING CALVES DO NOT USE IN CALVES TO BE PROCESSED FOR VEAL.		
For Turkeys: Control of infectious synovitis caused by <i>Mycoplasma agalactiae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	200 g/ton	3.333	For Calves (up to 250 lbs.): For an increased weight gain and improved feed efficiency.	0.1 mg/lb body weight/day	
For Turkeys: Control of haemorrhagic enteritis caused by <i>Escherichia coli</i> susceptible to chlorotetracycline. (Feed continuously 7-14 days)	400 g/ton	6.666	For Calves (250-400 lbs.): For an increased weight gain and improved feed efficiency.	25-70 mg/head/day	
For Turkeys: Turkey poulters not over 4 weeks of age. Reduction of mortality due to peritonitis caused by <i>Escherichia coli</i> susceptible to chlorotetracycline.	400 g/ton	6.666	For Growing Cattle (over 400 lbs.): For an increased weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses. WARNING: Zero-day withdrawal period.	70 mg/head/day	
For Turkeys: Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus enteritis) susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	25 mg/lb body weight/day		For Cattle: For the control of bacterial pneumonia associated with shipping fever complex susceptible to chlorotetracycline.	350 mg/head/day	
SHEEP For Growing Sheep: For an increased rate of weight gain and improved feed efficiency.	20-50 g/ton	0.333-0.833	For Beef Cattle (under 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline.	350 mg/head/day	
For Breeding Sheep: Reducing the incidence of (fetal) abortion caused by <i>Campylobacter fetus</i> infection susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.	80 mg/head/day		For Beef Cattle (over 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. WARNING: Withdraw 1 day prior to slaughter.	0.5 mg/lb body weight/day	
			For Calves, Beef, and Nonlactating Dairy Cattle: For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Treat for not more than 5 days) WARNING: Withdraw 1 day prior to slaughter.	10 mg/lb body weight/day	

TAKE TIME  OBSERVE DIRECTIONS

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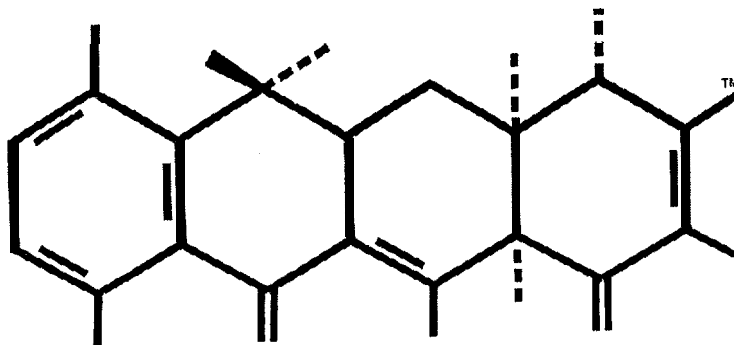
PennField Animal Health
24040 Industrial Rd.
Omaha, Nebraska 68144

Pennchlor 70TM

..... CHLORTETRACYCLINE

MEAL

(Type A Medicated Article)



FOR USE IN THE MANUFACTURE OF MEDICATED FEEDS

ACTIVE DRUG INGREDIENTS:

Chlortetracycline as Chlortetracycline Calcium Complex equivalent to 70 grams Chlortetracycline Hydrochloride/lb.
INGREDIENTS

Chlortetracycline, Calcium Carbonate, Roughage Products and Mineral 011.


See back panel for directions and warnings.

CAUTION: **For use in Dry Feeds ONLY - NOT FOR USE IN LIQUID FEED SUPPLEMENTS.**

NADA 138-935 APPROVED BY FDA

Restricted Drug: (California)
Use only as directed

NET WT.
50 lb (22.7 kg)

PennField[®] 

Pennchlor 70™

..... CHLORTETRACYCLINE

DIRECTIONS FOR USE

Indications to Use	Use Levels of Chlorotetracycline	Lbs. of Pennchlor 70™ per ton	Indications to Use	Use Levels of Chlorotetracycline	Lbs. of Pennchlor 70™ per ton
CHICKENS For Broiler/layer chickens: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.143-0.714	SWINE For Growing Swine: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.143-0.714
For Chickens: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	100-500 g/ton	1.43-2.86	For Swine: Reducing the incidence of cervical lymphadenitis (owl abscesses) caused by <i>Campylobacter</i> susceptible to chlorotetracycline.	50-100 g/ton	0.714-1.43
For Chickens: Control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	200-400 g/ton	2.86-5.72	For Breeding Swine: Control of leptospirosis (reducing the incidence of abortions and shedding of leptospires) caused by <i>Leptospira</i> susceptible to chlorotetracycline. (Feed continuously for 14 days)	400 g/ton	5.72
WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.			For Swine: Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Feed for not more than 14 days)	10 mg/lb body wt./day	
For Chickens: Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlorotetracycline. (Feed for 5 days)	500 g/ton	7.14	WARNING: Zero-day withdrawal period.		
WARNING: Do not feed to chickens producing eggs for human consumption. Withdraw 24 hours prior to slaughter.			CALVES, BEEF CATTLE, AND NONLACTATING DAIRY CATTLE WARNING: A WITHDRAWAL PERIOD HAS NOT BEEN ESTABLISHED FOR THIS PRODUCT IN PRE-FLUMINATING CALVES. DO NOT USE IN CALVES TO BE PROCESSED FOR VEAL.		
TURKEYS For Turkeys: Growing Turkeys: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.143-0.714	For Calves (up to 250 lbs.): For an increased weight gain and improved feed efficiency.	0.1 mg/lb body weight/day	
For Turkeys: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	200 g/ton	2.86	(250-400 lbs.) increased improved	25-50 mg/head/day	
For Turkeys: Control of hepatitis caused by <i>Mycoplasma meleagridis</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	400 g/ton	5.72	For Growing Cattle (over 400 lbs.): For an increased weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses.	70 mg/head/day	
For Turkeys: Turkey poult not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlorotetracycline.	400 g/ton	5.72	WARNING: Zero-day withdrawal period.		
For Turkeys: Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus enteritis) susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	25 mg/lb body wt./day		For Cattle: For the control of bacterial pneumonia associated with shipping fever complex susceptible to chlorotetracycline.	300 mg/head/day	
WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.			For Beef Cattle: Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline.	350 mg/head/day	
SHEEP For Growing Sheep: For an increased rate of weight gain and improved feed efficiency.	20-50 g/ton	0.286-0.714	For Beef Cattle (over 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline.	55 mg/lb body weight/day	
For Breeding Sheep: Reducing the incidence of (abortion) abortion caused by <i>Campylobacter fetus</i> infection susceptible to chlorotetracycline.	10 mg/head/day		WARNING: Withdraw 1 day prior to slaughter.		
WARNING: Zero-day withdrawal period.			For Calves, Beef, and Nonlactating Dairy Cattle: For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Feed for not more than 5 days)	10 mg/lb body weight/day	
			WARNING: Withdraw 1 day prior to slaughter.		

TAKE TIME  OBSERVE DIRECTIONS

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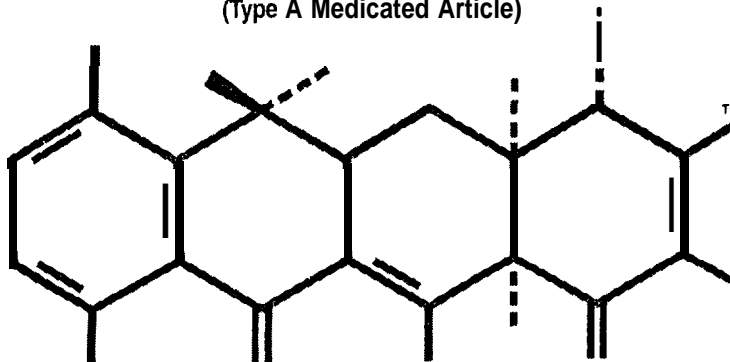
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Omaha, Nebraska 68144

Pennchlor 80TM

CHLORTETRACYCLINE

M E A L

(Type A Medicated Article)



FOR USE IN THE MANUFACTURE OF MEDICATED FEEDS

ACTIVE DRUG INGREDIENTS:

Chlortetracycline as Chlortetracycline Calcium Complex equivalent to 80 grams Chlortetracycline Hydrochloride/lb.

INGREDIENTS:

Chlortetracycline, Calcium Carbonate, Roughage Products and Mineral Oil.

See back panel for directions and warnings.

CAUTION: **For use in Dry Feeds** ONLY - NOT FOR **USE IN LIQUID** FEED SUPPLEMENTS.

NADA 138-935 APPROVED BY FDA

Restricted Drug: (California) -

Use only as directed

NET WT.
50 lb (22.7 kg)

Pennfield[®]



Pennchlor 80™

CHLORTETRACYCLINE

DIRECTIONS FOR USE

Indications for Use	Use Levels of Chlorotetracycline	Lbs. of Pennchlor 80™ per ton	Indications for Use	Use Levels of Chlorotetracycline	Lbs. of Pennchlor 80™ per ton
CHICKENS For Broiler/layer chickens: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.125-0.625	SWINE For Growing Swine: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.125-0.625
For Chickens: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	100-200 g/ton	1.125-2.5	For Swine: Reducing the incidence of cervical lymphadenitis (paw abscesses) caused by <i>Group E Streptococcus</i> susceptible to chlorotetracycline.	50-100 g/ton	0.625-1.25
For Chickens: Control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	200-400 g/ton	2.5-5.0	For Breeding Swine: Control of leptospirosis (reducing the instances of abortions and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to chlorotetracycline. (Feed continuously for 14 days)	400 g/ton	5.0
For Chickens: Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlorotetracycline. (Feed for 5 days) WARNING: Do not feed to chickens producing eggs for human consumption. Withdraw 24 hours prior to slaughter.	500 g/ton	6.25	For Swine: Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Feed for not more than 14 days) WARNING: Zero-day withdrawal period.	10 mg/lb body weight/day	
TURKEYS For Turkeys: Growing Turkeys: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.125-0.625	CALVES, BEEF CATTLE, AND NONLACTATING DAIRY CATTLE WARNING: A WITHDRAWAL PERIOD HAS NOT BEEN ESTABLISHED FOR THIS PRODUCT IN PRE-RUMINATING CALVES. DO NOT USE IN CALVES TO BE PROCESSED FOR VEAL.		
For Turkeys: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days)	200 g/ton	2.5	For Calves (up to 250 lbs.): For an increased weight gain and improved feed efficiency.	0.1 mg/lb body weight/day	
For Turkeys: Control of hemorrhitis caused by <i>Ureaplasma urealyticum</i> susceptible to chlorotetracycline. (Feed continuously 7-14 days)	400 g/ton	5.0	For Calves (250-400 lbs.): For an increased weight gain and improved feed efficiency.	25-70 mg/head/day	
For Turkeys: Turkey poult not over 4 weeks of age. Reduction of mortality due to paratyphoid caused by <i>Salmonella enteritidis</i> susceptible to chlorotetracycline.	400 g/ton	5.0	For Growing Cattle (over 400 lbs.): For an increased weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses. WARNING: Zero-day withdrawal period.	70 mg/head/day	
For Turkeys: Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus enteritis) susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	25 mg/lb body weight/day		For Cattle: For the control of bacterial pneumonia associated with shipping fever complex susceptible to chlorotetracycline.	350 mg/head/day	
SHEEP For Growing Sheep: For an increased rate of weight gain and improved feed efficiency.	20-50 g/ton	0.25-0.625	For Beef Cattle (under 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline.	350 mg/head/day	
For Breeding Sheep: Reducing the incidence of (vibronic) abortion caused by <i>Campylobacter fetus</i> infection susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.	80 mg/head/day		For Beef Cattle (over 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. WARNING: Withdraw 1 day prior to slaughter.	0.5 mg/lb body weight/day	
			For Calves, Beef, and Nonlactating Dairy Cattle: For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Feed for not more than 5 days) WARNING: Withdraw 1 day prior to slaughter.	10 mg/lb body weight/day	

TAKE TIME  OBSERVE DIRECTIONS

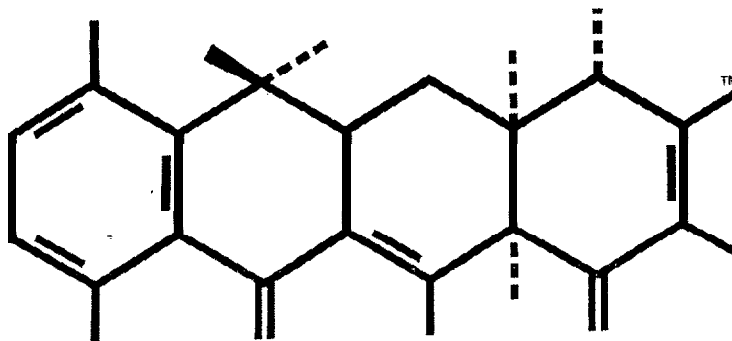
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Omaha, Nebraska 68144

Pennchlor 90™

● ooQoooo oooooos ooo CHLORTETRACYCLINE

M E A L
(Type A Medicated Article)



FOR USE IN THE MANUFACTURE OF MEDICATED FEEDS
ACTIVE DRUG INGREDIENTS

Chlortetracycline as Chlortetracycline Calcium Complex equivalent to 90 grams Chlortetracycline Hydrochloride/lb.
INGREDIENTS:

Chlortetracycline, calcium Carbonate, Roughage Products and Mineral Oil.

See back panel for directions and warnings.

CAUTION: For use In Dry **Feeds** ONLY - NOT FOR USE IN LIQUID FEED SUPPLEMENTS.
NADA 138-935 APPROVED BY FDA

Restricted Drug: (California) -
Use only as directed

NET WT.
50 lb (22.7 kg)

PennField®



Pennchlor 90™

..... CHLORTETRACYCLINE

DIRECTIONS FOR USE

Indications for Use	Use Levels of Chlortetracycline	lbs. of Pennchlor 90™ per ton	Indications for Use	Use Levels of Chlortetracycline	lbs. of Pennchlor 90™ per ton
CHICKENS For Broiler/layer chickens: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.111-0.555	SWINE For Growing Swine: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.111-0.555
For Chickens: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. (Feed continuously for 7-14 days)	100-200 g/ton	1.11-2.22	For Swine: Reducing the incidence of cervical lymphadenitis (owl abscesses) caused by <i>Group E Streptococcus</i> susceptible to chlortetracycline.	50-100 g/ton	0.555-1.11
For Chickens: Control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlortetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	200-400 g/ton	2.22-4.44	For Breeding Swine: Control of leptospirosis (reducing the instances of abortions and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to chlortetracycline. (Feed continuously for 14 days)	400 g/ton	4.44
For Chickens: Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. (Feed for 5 days) WARNING: Do not feed to chickens producing eggs for human consumption. Withdraw 24 hours prior to slaughter.	500 g/ton	5.55	For Swine: Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline. (Feed for not more than 14 days) WARNING: Zero-day withdrawal period.	10 mg/lb body weight/day	
TURKEYS For Turkeys: Growing Turkeys: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.111-0.555	CALVES, BEEF CATTLE, AND NONLACTATING DAIRY CATTLE WARNING: A WITHDRAWAL PERIOD HAS NOT BEEN ESTABLISHED FOR THIS PRODUCT IN PRE-RUMINATING CALVES. DO NOT USE IN CALVES TO BE PROCESSED FOR VEAL.		
For Turkeys: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. (Feed continuously for 7-14 days)	200 g/ton	2.22	For Calves (up to 250 lbs.): For an increased weight gain and improved feed efficiency.	0.1 mg/lb body weight/day	
For Turkeys: Control of hexamitiasis caused by <i>Ulexaria meleagris</i> susceptible to chlortetracycline. (Feed continuously 7-14 days)	400 g/ton	4.44	For Calves (250-400 lbs.): For an increased weight gain and improved feed efficiency.	25-70 mg/head/day	
For Turkeys: Turkey poulters not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.	400 g/ton	4.44	For Growing Cattle (over 400 lbs.): For an increased weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses. WARNING: Zero-day withdrawal period.	70 mg/head/day	
For Turkeys: Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus enteritis) susceptible to chlortetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	25 mg/lb body weight/day		For Cattle: For the control of bacterial pneumonia associated with shipping fever complex susceptible to chlortetracycline.	350 mg/head/day	
SHEEP For Growing Sheep: For an increased rate of weight gain and improved feed efficiency.	20-50 g/ton	0.222-0.555	For Beef Cattle: Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.	350 mg/head/day	
For Breeding Sheep: Reducing the incidence of (vibronic) abortion caused by <i>Campylobacter fetus</i> infection susceptible to chlortetracycline. WARNING: Zero-day withdrawal period	80 mg/head/day		For Beef Cattle (over 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline. WARNING: Withdraw 1 day prior to slaughter.	0.5 mg/lb body weight/day	
			For Calves, Beef, and Nonlactating Dairy Cattle: For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline. (Treat for not more than 5 days) WARNING: Withdraw 1 day prior to slaughter.	10 mg/lb body weight/day	

TAKE TIME  OBSERVE DIRECTIONS

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